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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,003	10/26/2000	M. Rigdon Lentz	LEN 101 CIP CON	7721

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EXAMINER	
BIANCO, PATRICIA	
ART UNIT	**PAPER NUMBER**
3761	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/699,003	LENTZ, M. RIGDON	
	Examiner	Art Unit	
	Patricia M. Bianco	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/22/05*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-12 and 16-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-12 and 16-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/24/05; 5/2/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claims 1-6, 8-15, and 16-20 are currently pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12, 16, 17 & 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Nakatani et al. 5,919,898 (IDS). Nakatani et al. disclose an adsorbent column (6) having an inlet (2) and an outlet (1) for allowing body fluid, such as blood or plasma, to pass through the adsorbent material (7) that is used for extracorporeal circulation treatment of a variety of diseases having a high concentration of interleukins (see col. 10, lines 16-34 for examples). Since Nakatani teaches that the column is used for extracorporeal circulation treatment, it is inherent that the inlet and outlet would be connected to tubing and a pump to pass the blood or plasma into the column and return the treated blood to the patient. The column is used to remove at least one cytokine receptor molecule desired, such as interleukins, such as IL-1, IL-2, IL-6, and IL-8 and/or TNF. The column has a compound or carrier immobilized on the adsorbent material

that is selective for removing the cytokine receptor molecule desired. With respect to inducing an immune response against diseased tissue, providing treatment using the device of Nakatani et al. would reduce the amount of a diseased tissue in the patient.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18 & 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakatani et al. ('898) in view of Bohm et al. 5,817,528 (IDS). Nakatani et al. discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the column has a compound or carrier immobilized on the adsorbent material that is an antibody or antibody fragments. Bohm et al. disclose a sterile pyrogen-free column having coupled protein for binding and removing substances from blood. The preferred proteins are disclosed to be antibodies, such as monoclonal antibodies using human IgG as the antigen (col. 4-col. 5). The column is disclosed as a module having a matrix material to which proteins can be coupled. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the column of Nakatani et al. and choose a column having antibodies, such as monoclonal antibodies using human IGs as the antigen as taught by Bohm et al., since it has been held to be within the general skill of a worker in the art to select a known

material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 and 8-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 7-9 of copending Application No. **11/153,524**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are merely a broader recitation of the claims in the conflicting copending application. Both claim a method for inducing an immune response against

transformed, infected or diseased tissue in a patient by performing the same method steps.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 7/25/05 with respect to the art rejections (see rejections above) have been fully considered but they are not persuasive. Applicant argues that Nakataini and Bohm, either separate or together, do not disclose an apparatus that removes cytokine receptors to induce an immune response. The examiner respectfully disagrees. Nakataini discloses that the column used may remove at least one cytokine receptor molecule desired, such TNF. The column has a compound or carrier immobilized on the adsorbent material that is selective for removing the cytokine receptor molecule desired. With respect to inducing an immune response against diseased tissue, providing treatment using the device of Nakatani et al. would reduce the amount of a diseased tissue in the patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June 11th, 2006

Patricia M Bianco
Primary Examiner
Art Unit 3761